EXHIBIT 1

Redacted

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA NORFOLK DIVISION

HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY
TO BE FILED UNDER SEAL
SUBJECT TO PROTECTIVE ORDER

In re: ZETIA (EZETIMIBE) ANTITRUST LITIGATION **This Document Relates to: *All Direct Purchaser Actions***	**MDL No. 2836** **Civil Action No. 18-md-2836-RBS-DEM**

DECLARATION OF JEFFREY J. LEITZINGER, PH.D.

Econ ONE Research, Inc.

November 18, 2019

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I. Introduction

1. I am an economist and Managing Director at Econ One Research, Inc., an economic research and consulting firm with offices in half a dozen cities around the country. I have master's and doctoral degrees in economics from UCLA and a bachelor's degree in economics from Santa Clara University. My doctoral work concentrated on the field within economics known as industrial organization, which involves among other things the study of markets, competition, antitrust, and other forms of regulation.

2. During the past nearly 40 years of my professional career, industrial organization has remained the principal focus of much of my work. I have worked on numerous projects relating to antitrust economics, including analyzing issues involving market power, market definition, and the competitive effects of firm behavior. I also have frequently assessed damages resulting from alleged anticompetitive conduct and have substantial experience in the calculation of damages in class action litigation. Additionally, I have significant experience with economic issues related to class certification in antitrust contexts.

3. I have testified as an expert economist in State and Federal courts, before a number of regulatory commissions and in international treaty arbitrations. I have been involved continuously in research regarding the pharmaceutical industry for over twenty years now. I am familiar with the economic and academic literature on the subject of generic drug competition, both as it operates normally and regarding strategies brand companies may employ to limit it. I previously have conducted economic analysis of impact and damages for purposes of class certification in a number of cases involving alleged anticompetitive conduct directed against AB-rated[1]

[1] "AB-rated" is a term the United States Food and Drug Administration ("FDA") uses to classify a generic drug product that has been found to be therapeutically equivalent to its branded counterpart. An AB-rated generic drug may be freely substituted for its branded counterpart at the pharmacy level without the prescribing physician's permission in most or all states. The FDA lists such substitutable drugs in its "Orange Book," the formal title of which is *Approved Drug Products With Therapeutic Equivalence Evaluations*. "Therapeutically equivalent" is a technical term for products that meet certain criteria including safety and efficacy, "pharmaceutical equivalence," "bioequivalence," and labeling and manufacturing standards. The definitions of therapeutic equivalence, pharmaceutical equivalence, and bioequivalence are listed in Sections 1.2 and 1.7 of the FDA's Orange Book. The FDA Orange Book can be found at http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf.

generic competition.[2] With few exceptions, the direct purchaser classes proposed in these cases were certified.[3] I also have provided expert opinions regarding market power, anticompetitive effects, procompetitive justifications, overcharges, and/or class-member settlement allocations in connection with the merits phase of many of these same cases. A detailed summary of my training, past experience, and prior testimony is shown in Exhibit 1.

4. Econ One is being compensated for the time I spend on this matter at my normal and customary rate of $825 per hour. Econ One also is being compensated for time spent by my research staff on this matter at their normal and customary hourly rates. No part of Econ One's compensation is contingent on the outcome of this matter.

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[2] *In re Intuniv Antitrust Litigation*, No. 16-cv-12653 (D. Mass.); *In re Loestrin 24 FE Antitrust Litigation*, MDL No. 2472 (D.R.I.); *In re Niaspan Antitrust Litigation*, MDL No. 2460 (E.D. Pa.); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litigation*, No. 14-md-2503-DJC (D. Mass.); *In re Celebrex (Celecoxib) Antitrust Litigation*, No. 2:14-cv-00361 (E.D. Va.); *In re Lidoderm Antitrust Litigation*, No. 14-md-2521 (N.D. Cal.); *In re Prograf Antitrust Litigation*, No. 1:11-cv-10344-RWZ (D. Mass.); *In re Wellbutrin XL Antitrust Litigation*, No. 08-2431 (E.D. Pa.); *In re Relafen Antitrust Litigation*, Master File No. 01-12239-WGY (D. Mass.); *In re Tricor Direct Purchaser Antitrust Litigation*, C.A. No. 05-340 KAJ (D. Del.); *Meijer, Inc. et al. v. Warner Chilcott Holdings III, Ltd., et al.*, No. 05 Civ. 2195 CKK (D.D.C.) (involving the drug Ovcon 35); *In re Nifedipine Antitrust Litigation*, No. 03-MS-223 (D.D.C.); *In re K-Dur Antitrust Litigation*, No. 2:01-cv-01652 (D.N.J.); *Louisiana Wholesale Drug Co., Inc. v. Sanofi-Aventis, et al.* No. 1:07-cv-07343-HB (S.D.N.Y.) (involving the drug Arava); and *In re Flonase Direct Purchaser Antitrust Litigation*, Master File No. 2:08-cv-03149 (E.D. Pa.). I also have offered testimony (either by deposition or declaration or both) regarding aggregate overcharge damages suffered by classes of direct purchasers in numerous cases including those listed above as well as: *In re Cardizem CD Antitrust Litigation,* MDL No. 1278 (E.D. Mich.); *In re Buspirone Patent & Antitrust Litigation,* MDL No. 1413 (S.D.N.Y.); *In re Remeron Direct Purchaser Antitrust Litigation*, No. 03-CV-0085 (D.N.J.); *North Shore Hematology-Oncology Associates, P.C. v. Bristol-Myers Squibb Co.,* (D.D.C.) (involving the drug Platinol); *In re Terazosin Hydrochloride Antitrust Litigation,* MDL No. 1317 (S.D. Fla.); and *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, MDL No. 1383 (E.D.N.Y.).

[3] I understand that in *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 2:06-cv-01797 (E.D. Pa.) (involving the drug Provigil) the district court certified a class of 22 direct purchasers, but the Third Circuit vacated and remanded, finding the court had not adequately explained why joinder was impractical. *In re Modafinil Antitrust Litigation*, 837 F.3d 238 (3d Cir. 2016). On remand, the district court denied certification to a proposed class of 24-25 members, and some of the former class members proceeded individually. 2:06-cv-01797 (E.D. Pa.), Dkt. No. 1081 (Jan. 21, 2018) (stating 16 former class members were proceeding against the remaining defendant); the case was settled in November 2018 (Stock Exchange Letter Intimation of Settlement in re Modafinil Antitrust Litigation in US with Certain Plaintiffs, available at https://www.sunpharma.com/node/236140). In addition, I understand that the Court recently denied class certification on "numerosity" grounds in *In re AndroGel Antitrust Litig. (No. II)*, 1:09-MD-2084, 2018 WL 3424612 (N.D. Ga. Jul. 16, 2018).

II. Assignment, Materials Reviewed and Summary of Conclusions

5. FWK Holdings, LLC, Rochester Drug Co-Operative, Inc., and Cesar Castillo, Inc. seek to represent a proposed class of direct purchasers (collectively "Plaintiffs") of branded and generic Zetia (the "Class").[4] The Defendants in this case are Merck & Company, Inc., Merck Sharp & Dohme Corporation, Schering-Plough Corporation, Schering Corporation, and MSP Singapore Company LLC (collectively, "Merck"); Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA (collectively "Glenmark"); and Par Pharmaceuticals, Inc ("Par"). Zetia is Merck's branded version of ezetimibe, which is an "inhibitor of intestinal cholesterol."[5] Plaintiffs allege that the Defendants entered into an unlawful agreement which delayed and limited generic competition.[6] Plaintiffs further allege that the Class was overcharged as a result of this agreement.[7]

6. I have been asked to undertake several tasks in connection with the class certification stage of this case. First, I have been asked to form an opinion about the impact of Defendants' alleged conduct on the prices Class members paid for ezetimibe. Second, I have been asked to analyze whether proof of widespread antitrust injury (i.e., the payment of at least some overcharge) among members of the Class can be accomplished in this case with evidence that is predominantly common and class-wide. Third, I have been asked whether the aggregate amount of overcharges incurred by the proposed Class can be calculated in this case on a Class-wide, formulaic basis and provide an illustrative calculation of overcharges.

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[4] I understand from counsel that for purposes of my analysis the Class is defined as: All persons or entities in the United States and its territories that purchased Zetia or generic Zetia in any form directly from Merck, Glenmark/Par, or any agents, predecessors, or successors thereof from July 1, 2012 until June 11, 2017. Excluded from the proposed Class are defendants Merck, Glenmark and Par, and their officers, directors, management, employees, parents, subsidiaries, or affiliates, and the government of the United States and all agencies thereof, and all state or local governments and all agencies thereof.

[5] Zetia label, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021445s033lbl.pdf.

[6] Direct Purchaser Plaintiffs' Amended Consolidated Class Action Complaint and Demand for Jury Trial, dated June 27, 2019 ("Complaint"), ¶¶ 4, 6.

[7] Complaint, ¶ 7.

7. For purposes of this Declaration, I have been asked to assume that, but for the conduct at issue in this case, generic entry would have occurred as early as July 2012. I've been asked to further assume that there would have been five generic competitors on the market, including an authorized generic, as of December 2016 (the date that Glenmark/Par actually entered the market).[8]

8. In performing this analysis, my staff and I collectively have reviewed the Complaint, documents produced in discovery, sales data provided by Merck, Par, and other generic manufacturers, other publicly available data, and scientific literature regarding the nature and effect of generic competition. A list of the materials we have reviewed is attached as Exhibit 2.

9. As I explain below, the price benefits associated with AB-rated generic competition are predictable, substantial, and market-wide. Generics are essentially commodities and sellers compete with each other and against the reference brand primarily on price. As a result, generic versions of a drug are typically sold at a small fraction of the brand price--and discounts off the brand price increase with increased numbers of generic competitors. In addition, competition from generics also can lead to price reductions on the part of the brand manufacturer itself, further enhancing the resulting savings in prescription costs. Given these price benefits and the well-developed proactive process through which generics are utilized within the distribution system, generics typically displace most of the reference brand product within its prescription base, greatly reducing the cost of filling those prescriptions.

10. Against this backdrop, and based on the work my staff and I have undertaken in this case, I have concluded that:

    a. The delay in generic competition, both as to its initial launch and the launch of an authorized generic by Merck, alleged in this case would cause the amounts paid by Class members for ezetimibe used to fill Zetia prescriptions to be substantially higher than otherwise, resulting in widespread overcharges.

[8] According to the Complaint, "Glenmark launched its generic product in partnership with Par (as planned)." Complaint, ¶ 259.

b. Based upon evidence which is common to members of the proposed Class, I also conclude that the delay of and limits on generic competition I have been asked to assume for these purposes very likely caused each proposed Class member to pay at least some overcharge in connection with its ezetimibe purchases.

c. Finally, I conclude that the calculation of aggregate overcharges for the Class in this case is readily susceptible to formulaic analysis and will not require individualized inquiry as to each Class member. I provide an illustrative calculation of overcharges below.

The sections below set forth the basis for these conclusions.

III. The Role of Generic Competition

11. The pharmaceutical industry is oriented, to a great extent, around the development and monetization of intellectual property. Manufacturers of branded pharmaceuticals devote resources to the development of new drugs. The incentive for this effort is the substantial profit that often derives from commercial success.[9]

12. One of the reasons for these profits is the temporary legal protection from competition that newly developed drugs enjoy. In that regard, developers of new products often obtain patents covering the formulation of the pharmaceutical compound, its manufacturing process or its application.[10] Patents expire generally within twenty years of filing.[11] Patents that, according to the drug developer, apply to their drugs are listed in the FDA's Orange Book.[12] These filings are made available to the public, including would-be generic manufacturers.

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[9] Congressional Budget Office, "How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," July 1998 (hereafter, "CBO Study"), p. 3.

[10] Federal Trade Commission, "Generic Drug Entry Prior to Patent Expiration," July 2002 (hereafter, "2002 FTC Study"), p. 41.

[11] U.S. Patent and Trademark Office, "General Information Concerning Patents," available at https://www.uspto.gov/patents-getting-started/general-information-concerning-patents.

[12] 2002 FTC Study, p. 5; *Mylan Pharmaceuticals, Inc. v. Tommy G. Thompson, et al.*, 268 F.3d 1323, 1326 (Fed. Cir. 2001), p. 1325.

13. In 1984, Congress passed the Hatch-Waxman Act ("Hatch-Waxman") to "make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962" and "to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval."[13] Under Hatch-Waxman, generic manufacturers are allowed to seek to bring generic drugs to market under an abbreviated application process ("Abbreviated New Drug Application" or "ANDA").[14] Under Hatch-Waxman, the FDA must wait until five years after its approval of the brand's New Drug Application ("NDA") involving a new chemical entity to grant generic approval.

14. A generic manufacturer entering the market under an ANDA avoids most of the cost associated with development, testing and FDA approval for a new drug. They also have the FDA's endorsement regarding the therapeutic equivalence of their products to the brand. When a generic product meets FDA standards for safety and efficacy, the FDA gives the product an "AB" rating. This rating is the FDA's assurance to physicians, pharmacists, and patients that the product will have the same therapeutic effects, safety, and efficacy as the brand. Once an AB-rated generic enters the market, its lower price, state laws and regulations, managed care policies, and pharmacy incentives combine to induce rapid and substantial substitution in place of the branded version when it comes to filling prescriptions. This generic-for-brand substitution greatly reduces the overall cost of supplying the brand prescription base.

15. Since the passage of Hatch-Waxman, generics have become an especially powerful engine for lower drug prices.[15] Given that, conduct that delays or limits generic

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[13] H.R. Rep. 98-857 (I), 1984 U.S.C.C.A.N. 2647.

[14] *FTC v. Actavis, Inc.,* 133 S. Ct. 2223 (2013) (hereafter, "*Actavis*"), p. 2228 ("once the FDA has approved a brand-name drug for marketing, a manufacturer of a generic drug can obtain similar marketing approval through use of abbreviated procedures. The Hatch-Waxman Act permits a generic manufacturer to file an [ANDA] specifying that the generic has the 'same active ingredients as,' and is 'biologically equivalent' to, the already-approved brand-name drug."). See also, 21 U.S.C. § 355(j).

[15] Association for Accessible Medicines, "Generic Drug Access & Savings in the U.S.: Access in Jeopardy," 2018, p. 4 ("In 2017, generics generated a total of $265 billion in savings."); Generic Pharmaceutical Association, "Generic Drug Savings in the U.S.," 2013, p. 1 ("Over the 10-year period 2003 through 2012, generic drug use has generated more than $1.2 trillion in savings to the health care system."); Federal Trade Commission, "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions," January 2010

competition (as alleged in this case) delays or limits those price benefits, thereby creating substantial overcharges in the amounts paid to fill prescriptions for the affected drug. In effect, conduct which delays generic competition extends the control that a brand company maintains over its prescription base, artificially extending the temporary period of competitive protection contemplated by the Hatch-Waxman framework.

16. In its ANDA filing, a generic manufacturer must declare its position with respect to the patents listed in the Orange Book for the corresponding brand (or "reference") drug. In that regard, the generic company can certify that its product would not infringe the listed patents or that those patents are invalid or unenforceable--referred to as a "Paragraph IV" ANDA filing--signaling its intention to enter the market notwithstanding the patents listed in the Orange Book.[16] Once the generic company makes its Paragraph IV filing, the brand company has 45 days to commence infringement litigation against the generic should it dispute that certification. The commencement of litigation triggers an automatic stay by the FDA for up to 30 months in regards to its approval of the generic ANDA application.[17]

17. Often times Paragraph IV filings by one generic manufacturer are followed by similar filings by other manufacturers. Once there are multiple generic sellers, the drug is essentially available as a commodity. This means, as the CBO has recognized, "[s]ince generic prices tend to fall as the number of producers rises, generic manufacturers are most profitable when they are one of the first to enter a market."[18] Indeed, under Hatch-Waxman, the first generic to file and successfully pursue a

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(hereafter, "2010 FTC Study"), p. 2 (The FTC estimated that pay-for-delay agreements, which delay the onset of generic competition, cost American consumers $3.5 billion per year – $35 billion over 10 years); *id.* at p. 8 (within a year, on average, generic prices were 85% lower than the pre-generic brand price and generics had captured 90% of the brand sales.).

[16] *Actavis*, p. 2228.

[17] 2002 FTC Study, p. ii; Federal Trade Commission, "Authorized Generics: An Interim Report," June 2009, (hereafter, "2009 FTC Study"), p. 2. The patent holder can file suit after 45 days, but such a later-filed suit does not trigger the automatic 30-month stay.

[18] CBO Study, p. 32. See also, 2011 FTC Study, Executive Summary ("During [the first 180 days], because of the absence of competition, both the generic drug price and the first-filer's revenues are significantly higher than they would be when there are additional generic competitors.").

Paragraph IV challenge to the patents on file by a brand product (the "first filer") obtains 180 days of exclusive protection as the sole ANDA generic supplier.[19] That exclusivity is highly valuable to generic manufacturers.[20]

18. Often times, brand manufacturers respond to generic competition by engaging in direct price competition with generic manufacturers, launching what is called an "authorized generic" or an "AG" version of the brand product (basically the same product as the brand, sold under the brand's own NDA, but marketed as a generic). Since authorized generics don't require a new ANDA, their ability to enter the market is not limited by the 180-day ANDA exclusivity granted to the first filer. As a result, "…pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'"[21] Of course, as with any additional generic competitor, the launch of an AG engenders increased competition and lower prices.[22] A study by Berndt, et al. involving three drugs for which there were authorized generics found that, "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand."[23]

19. This sets up a dynamic that has direct relevance to the allegations in this case. The first ANDA filer ("first-filer", for short) earns a valuable right to 180-day exclusivity following its product launch. That launch comes at great cost to the brand as the lower-priced generic replaces most of its sales. The brand has the unique ability to

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[19] *Actavis*, pp. 2228-2229. See also, Federal Trade Commission, "Authorized Generic Drugs: Short-Term Effects and Long-Term Impact," August 2011 (hereafter, "2011 FTC Study").

[20] *Actavis*, p. 2229 ("...this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars.'"). See also, Grabowski, H., G. Long, and R. Mortimer, "Recent trends in brand-name and generic drug competition," *Journal of Medical Economics*, December 2013, p. 2.

[21] Hassett, K. A. and R. J. Shapiro, "The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals," *Sonecon*, May 2007, p. 3.

[22] See, for example, 2011 FTC Study and IMS Consulting, "Report to PhRMA, Assessment of Authorized Generics in the U.S.," Spring 2006 (hereafter, "2006 IMS Study").

[23] Berndt, E., R. Mortimer, A. Bhattacharjya, A. Parece and E. Tuttle, "Authorized Generic Drugs, Price Competition, and Consumers' Welfare," *Health Affairs*, v. 26, n. 3, May/June 2007, p. 796.

mitigate some of that cost by launching an AG during the exclusivity period. However, the ensuing generic competition--between the first-filer and the AG--also undercuts the value of that exclusivity to the first-filer.

20. As a result, a potentially lucrative bargain for both sides becomes available. By agreeing to forego the launch of an AG during the exclusivity period, the brand creates added value for the first-filer that it can then offer in trade for agreement by the first-filer to delay its generic launch. For the brand, its loss of sales and profits from generic competition is delayed, a result which is much more valuable than the lost AG opportunity. For the generic, while its revenues and profits are also delayed, the benefits derived from the lack of AG-competition during the exclusivity period can readily outweigh the cost of delay. The losers in this bargain are those who pay for the drug. They pay higher costs during the agreed upon delay in generic launch--they don't experience any of the generic price benefits they otherwise would have received during this period. They also pay more during the exclusivity period that follows the eventual generic launch because, absent competition from an AG, generic prices are higher. As described below, Plaintiffs allege that this is the bargain reached in this case.

IV. Background

21. Zetia is the brand name for ezetimibe, which is an "inhibitor of intestinal cholesterol."[24] Zetia received FDA approval in 2002.[25] [redacted]

22. In 2010, Glenmark filed a Paragraph IV ANDA application for a generic version of Zetia. Plaintiffs allege that "Merck and Glenmark entered into an agreement that, …, unlawfully allocated the market for ezetimibe."[27] According to Plaintiffs "as a quid pro quo for Glenmark/Par's agreement to drop the patent challenge and delay

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[24] Zetia label, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021445s033lbl.pdf.

[25] FDA approval letter, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/21445ltr.pdf.

[26] [redacted].

[27] Complaint, ¶ 187.

market entry for over five years, Merck promised not to launch a competing authorized generic version of Zetia during Glenmark/Par's eventual 180-exclusivity period (the 'no-AG agreement')."[28] Glenmark/Par did finally enter the market in December 2016.[29] Merck did not launch a competing AG. Five additional manufacturers (Amneal, Apotex, Sandoz, Sun, and Teva) entered the market with generic versions of Zetia in June 2017.[30] Followed by three additional generic manufacturers at the end of 2017/beginning of 2018.[31] Plaintiffs allege that but for the "reverse payment agreement," generic entry would have occurred earlier and included an AG.[32]

V. Antitrust Injury

23. In my opinion, there is evidence common to members of the proposed Class which shows that a delay in the initial generic launch coupled with a delay in the launch of Merck's AG very likely would cause each member of the Class to incur at least some overcharge and therefore suffer antitrust injury. This evidence consists of i) literature and prior studies showing that generic competition (both generally and from AGs) results in prices that are substantially below the brand's prices and that the vast majority--often upwards of 90 percent--of the brand prescription base is typically converted to generics along with those lower prices; ii) forecasts prepared by Merck and generic competitors that [redacted]; iii) market results following actual generic entry in 2016 that bore out these predictions; and iv) the fact that, as intermediaries in pharmaceutical distribution, Class members would be expected to experience outcomes that reflect these market-wide patterns.[33]

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[28] *Id.*, ¶ 193.

[29] Par transaction data; Complaint, ¶ 259.

[30] Manufacturer data.

[31] Manufacturer data.

[32] Complaint, ¶¶ 209-214.

[33] These outcomes are borne out in my own prior experience with a number of drugs in other generic delay cases. In each case, generic competition substantially reduced the acquisition costs of the drug.

A. Economic Literature Pertaining to the Effects of Generic Competition

24. There is an extensive body of published research concerning the effects of generic competition in pharmaceutical markets.[34] The principal conclusions of that literature are that generic products enter the market at substantially lower prices than their branded counterparts and capture a significant share of the combined product (brand and generic) unit sales. Taken together, these findings mean that conduct which forestalls that generic entry generally will result in inflated prices for the brand prescription base.

25. To take just a few examples, a study by Saha, et al. (2006) investigated 40 drugs that experienced generic entry between July 1992 and January 1998. They found that generic prices averaged 76 percent of the brand price one month after generic entry and 54 percent of the brand price after one year.[35] According to a 2010 FTC Study, "in a mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug price."[36] Lichtenberg and Duflos found that when generic competitors entered the market, prices declined by approximately 60 percent.[37]

26. The literature also shows that the pricing benefits created by generic competition increase with the number of competitors. Reiffen and Ward find that "generic drug prices fall with increasing number of competitors."[38] They find that the "effect of increased competition on prices continues at least until the fifth firm enters, but is

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[34] See, for example, the references listed in Saha, A., H. Grabowski, H. Birnbaum, P. Greenberg and O. Bizan, "Generic Competition in the US Pharmaceutical Industry," *International Journal of the Economics of Business*, n. 1, v. 13 (February 2006), pp. 15-38 (hereafter, "Saha, et al. (2006)").

[35] Saha, et al., (2006), p. 28.

[36] 2010 FTC Study, p. 8. See also, IMS Institute for Healthcare Informatics, "Price Declines after Branded Medicines Lose Exclusivity in the U.S.," January 2016.

[37] Lichtenberg, F. and G. Duflos, "Time Release: The Effect of Patent Expiration on U.S. Drug Prices, Marketing, and Utilization by the Public," *Medical Progress Report*, Center for Medical Progress at the Manhattan Institute, No. 11, October 2009, p. 5.

[38] Reiffen, D. and M. Ward, "Generic Drug Industry Dynamics," *The Review of Economics and Statistics*, February 2005, 87(1): 37-49 (hereafter, "Reiffen and Ward (2005)"), p. 37.

not likely to be important after the eighth firm enters."[39] Saha, et al., (2006) find that "each additional generic manufacturer induces nearly a 2.3% monthly decrease in the value of the generic-to-brand price ratio."[40] The authors note that "this result is consistent with the economic reasoning that the degree of competition is positively related to the number of producers in the market."[41] A study by the FDA found that the average size of generic discounts relative to brand prices increased several fold as the number of generic competitors increased from one to six.[42]

27. The competitive benefits of AG competitors also are well documented in the literature. According to a 2011 FTC study, with AG competition, generic prices were 7-14 percent lower than otherwise.[43] IMS Consulting found that the generic discount to the brand price was 16 percent higher when there was an AG in the market.[44]

28. The broad pricing benefits associated with generic competition arise both because generics have lower prices than the brand and because, once generics become available, there is typically widespread utilization of generics to fill prescriptions within the brand prescription base. This broad conversion to generics is well documented in the literature. A 2009 FTC Study found that generics captured between approximately 72 and 85 percent of the brand's sales in the first six months.[45] A 2010 FTC Study concluded that, one year following initial entry,

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[39] Reiffen and Ward (2005), p. 49.

[40] Saha, et al., (2006), p. 29. (Citations omitted.)

[41] Saha, et al., (2006), p. 29.

[42] Food and Drug Administration, "Generic Competition and Drug Prices,". Available at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm.

[43] 2011 FTC Study, pp. ii, 33, 47-48.

[44] 2006 IMS Study.

[45] 2009 FTC Study. See also Grabowski, H., M. Kyle, R. Mortimer, G. Long and N. Kirson, "Evolving Brand-Name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act," *Health Affairs*, Vol. 30, no. 11, 2011 (noting that brand drugs facing first generic entry in 2007-2008 retained 15 percent of the volume a year after generic entry). This is consistent with industry experience. PharmaCare, a pharmacy benefit manager wholly-owned by CVS, shifted nearly 95 percent of its Zocor patients to generics during the first month of their availability. (CVS Caremark Press Release, "PharmaCare's Aggressive Outreach Successfully Shifts 95% of its Zocor Market Share to Generic Simvastatin in One Month,

generics typically accounted for 90 percent of the corresponding brand prescription base.[46]

29. There also is evidence in the literature that generic competition can lead to better prices for the brand itself. According to a study by the CBO, "[a] statistical analysis of pharmaceutical prices shows that purchasers tend to obtain higher discounts from manufacturers on brand-name drugs when generic substitutes are available… ."[47] A 2011 FTC Study found that post-generic entry brand prices were 4-11 percent below the pre-generic level.[48] More typically, especially in the last 10 years or so as noted above, brand manufacturers compete with generics by offering (or licensing) AGs at a fraction of the price previously charged for the brand itself.

30. Viewed as a whole, the existing literature pertaining to generic competition contains the following findings:

i) generic drugs have substantially lower prices than their branded counterparts;

ii) more generic competitors lead to higher discounts off the brand price;

Generating Significant Savings for Clients," August 17, 2006). Another pharmacy benefit manager, Medco, observed that generic dispensing rates for Allegra were nearly 90 percent within 30 days of the generic becoming available. (Medco Press Release, "New Analysis: Recent Generic Blockbusters Show Huge Gains; Consumer Adoption Rates Accelerate," January 18, 2006 (hereafter, "Medco Press Release")). Medco also claims that through its mail-order pharmacies, it "regularly achieves a near-95 percent substitution rate within the first week for new generic chronic-care medications." (Medco Press Release). Such rapid generic penetration has led the president of generic manufacturer Par Pharmaceuticals to observe that "[o]vernight, quite literally, the branded [drug] companies are losing their entire franchise," as a result of generic entry. (Levy, S.,"Why Authorized Generics Are Making a Comeback," *Drug Topics*, November 3, 2003).

[46] 2010 FTC Study, p. 8.

[47] CBO Study, p. 24. Unlike some of the earlier literature, which focused just on list prices, the CBO Study used data including discounts from brand list prices.

[48] 2011 FTC Study, pp. 52-54 ("The average ANDA-Only contemporaneous brand price is 4% lower than the pre-entry brand prices in the unweighted sample and 11% lower than the pre-entry brand prices in the sales-weighted sample. During exclusivity, the presence of an AG lowers relative brand wholesale prices between 7.7% and 12.2%, depending on the controls that are included in the regression model." (Citations omitted.)).

iii) within a few months of their launch, generics typically capture the vast majority of the brand prescription base; and

iv) competition from generics often leads to the launch of an AG and/or direct price concessions from the brand manufacturer.

The literature clearly shows that conduct which delays or limits generic competition would be expected to broadly inflate prices across the relevant prescription base.

B. The Manufacturers' Internal Generic Penetration Models and Forecasts

31. [redacted]

32. [redacted]

[49] [redacted]

[redacted]

[redacted] [redacted]

[redacted] [redacted]

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52 [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted].

C. Actual Zetia Experience

36. [redacted]

[redacted]

[60] [redacted]

[redacted].

[redacted]

D. Class-wide Antitrust Injury

38. As noted above, I have been asked by Plaintiffs' counsel to determine whether evidence that is common to Class members can be used to show widespread impact among them. I have been asked, for purposes of this Declaration, to assume that generic entry would have occurred as early as July 2012 absent the challenged conduct. See Exhibit 7. I have concluded that evidence common to Class members shows that delay in generic entry of the sort I have been asked to assume would very likely have caused each proposed Class member to pay at least some overcharge (and, in that way, incur antitrust injury.)

39. The common evidence I refer to above is: i) existing studies of generic competition and its effects; ii) forecasts produced by Defendants and other generic manufacturers [redacted]; and iii) the actual experience following generic entry for Zetia in 2016. In addition, I also take note of the fact Class members are intermediaries in the chain of distribution--which, as described below, enhances the evidentiary significance of the market outcomes described above as to impact for each Class member.

40. In particular, the literature shows that generic products enter the market at substantially lower prices than their branded counterparts (indeed, increasingly so as

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[65] Manufacturer data. See Exhibit 5.

[66] Manufacturer data. See Exhibit 6.

more generic competitors, such as an AG, enter the market) and capture a significant share of the combined product (brand and AB-rated generic) unit sales. The company forecasts [redacted]. Lastly, the actual experience with generic competition when it finally did emerge presents a similarly compelling competitive picture--high rates of generic penetration and steep generic discounts that increased as more generic competitors entered the market. Delay in generic entry would have precluded these price benefits and caused overcharges.

41. [redacted]

42. As mentioned above, it is important to recognize this distributional role of Class members in assessing the implications of these market outcomes for individual Class member impact. They are nearly all wholesalers or retailers supplying product to broad cross-sections of the patient community.[67] It is therefore reasonable to expect that their experience would be reflective of the market-wide effects described above. Put another way, there is no reason to suppose that any Class member served only that small fraction of the Zetia prescription base, if any, that would not have benefited from a pricing standpoint with earlier (and unrestricted) generic competition.[68]

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[67] Based upon the Class definition, transaction data showing sales to direct purchasers, and instructions from counsel regarding the status of certain entities, I have identified 70 Class members (including the named plaintiffs and assignees--see Exhibit 8). Exhibit 9 shows the geographic dispersion of these Class members.

[68] These outcomes are borne out in my own prior experience (referenced above) with a number of drugs. In each case, generic competition substantially reduced the acquisition costs of the drug.

43. [redacted]

[redacted]

69 [redacted]

[redacted]

44. [redacted]

45. The likelihood of lower prices associated with generic volumes purchased by Class members during the Class period is also very high. This is because, based upon the generic entry scenario I have been given for purposes of this work, the market environment in which those purchases would have occurred absent the challenged conduct would have included four additional generic competitors (beyond the sole generic seller (Glenmark/Par) that was available during this period).[71] The literature, [redacted] and the actual Zetia generic experience clearly show that more

[71] Glenmark/Par was the sole generic selling from December 12, 2016 through June 11, 2017.

generic competitors predictably lead to larger discounts relative to the brand.[72] As a result, the generic prices paid by each Class member very likely were higher than they would have been absent the challenged conduct.

46. [redacted]

[redacted]

[redacted] As a matter of economic logic, the likelihood of antitrust injury--which is to say, at least some overcharge--on the part of individual Class members is the likelihood that,

[72] Sections V.A.-V.C.

with earlier unrestricted generic competition, the Class member would have experienced any one of the three effects described above: increased purchases of lower priced generic in place of the brand it did purchase; reduced prices on brand volumes it continued to purchase; or, lower prices for the generic product it did buy after the generic entered in December of 2016. As the foregoing discussion makes clear, these effects are substantial in size and broad in scope across the market. I find it highly unlikely, as a result, that any Class member would not have participated in at least one of these three price benefits with earlier unrestricted generic competition. In other words, I conclude that the delay in generic competition I have assumed for purposes of my analysis very likely caused antitrust injury as to each Class member assuming entry on July 1, 2012.[73]

VI. Overcharge Methodology

48. In my past work, I frequently have analyzed aggregate overcharges associated with delayed generic entry for direct purchaser classes. In all of those instances, I was able to estimate the aggregate overcharge using a class-wide formula that did not require analysis of the circumstances pertaining to individual class members. In several cases, my overcharge estimates were submitted to the court for purposes of its review and approval of class-wide settlements. I find that, just as in these prior cases, a formulaic approach can be applied here to estimate aggregate overcharges.

49. The general formula I have consistently applied for purposes of calculating Class-wide overcharges associated with the period for which generic entry was delayed is set forth below:

[73] The current Class definition includes buyers of brand and generic Zetia beginning with the start of the alleged generic delay period, July 1, 2012. If it is determined that the generic delay period commences at a later point in time and the Class definition is not amended to account for that, there may then be Class members (as the Class is currently defined) who did not purchase Zetia or generic Zetia after the start of the delay period and therefore would not have incurred overcharges as a result of that delay.

Overcharges = Vol * [ActPrice * ((GP * GD)+(1 - GP) * BD)]

Where:

Vol=	Aggregate Class purchases during the affected period
ActPrice=	Average price paid for those volumes by the Class
GP=	Generic penetration rate
GD=	Average generic discount relative to the brand price
BD=	Average brand discount resulting from generic competition

50. I also have calculated overcharges on generic purchase volumes after the generic enters the market. For generic purchases, the overcharge formula is straightforward. The overcharge is equal to the actual generic volumes multiplied by the difference between actual and but-for generic prices.

51. I would apply this same formulaic approach to measure Class-wide overcharges in this case. "Vol" is readily assessable using the transaction data provided by Defendants and other manufacturers through the discovery in this case. "ActPrice" can be calculated from those same data. "GP," "GD," and "BD" can all be estimated on a Class-wide level using various benchmarks as described below. Those benchmarks draw upon the actual experience at a market-wide level drawn from data produced by Defendants and other manufacturers or from their collective projections about the impact of generic competition on prices. No individualized inquiries regarding the circumstances of particular Class members are needed. Hence, there is no obstacle that prevents formulaic Class-wide assessment of overcharges. Arguments may arise about the choice of benchmarks or the best manner to use the underlying data or forecasts, but there is no serious argument against the feasibility of analyzing overcharges in this fashion. By way of demonstration as to the feasibility of this formulaic method for this case, I have prepared the overcharge illustration set forth below.

52. Before turning to that, I want to address an argument that has been raised on some occasions in the past--i.e., that the aggregate formulaic analysis I propose presumes

that individual Class members each experience the same total or unit overcharge or that the generic penetration and pricing parameters that pertain to the Class in the aggregate must necessarily apply to each Class member individually. And so, the argument goes, individual analysis of overcharges is necessary to support the premise underlying the aggregate model.

53. This argument is misplaced. There is no underlying premise of that sort embedded within my aggregate formulaic approach. Indeed, purely as a technical matter of the model design, it is agnostic as to whether each Class member contributes in the same way to the total, whether they contribute in different amounts or whether some don't contribute at all.[74] And, since the ability to undertake this formulaic analysis does not depend upon any particular pattern of overcharges across Class members, it is not necessary to undertake individual overcharge analysis to validate the aggregate model.

A. Prices and Penetration Absent the Illegal Conduct

54. As noted above, Counsel has provided a generic entry scenario representing the likely market outcomes absent the challenged conduct. See Exhibit 7. This generic entry scenario dictates the initial starting point for generic competition, as well as the number of generic competitors at various points in time following the date of initial entry. Based upon this scenario, I can use data and documents produced in this case, along with some publicly available data to calculate generic penetration, generic discounts, and brand discounts that would have prevailed at each point in time. I describe the methodology below.[75]

55. To model generic penetration under the alternative generic entry date, I calculate actual generic penetration rates (generic sales relative to total ezetimibe volume) on a quarterly basis following the December 2016 generic entry and then backcast those

[74] Stepping outside the implications of the aggregate overcharge model taken by itself, other parts of my analysis particularly as to Class-wide impact, preclude this possibility.

[75] Based on my past experience and work on this case to date, I regard this methodology as reasonable and reliable. That said, the inputs I employ within the methodology set forth below do not represent my final opinions on the matter and may change between now and when I ultimately submit my final report on damages. However, changes in the inputs won't change the formulaic nature of this overcharge model or the ability through its implementation to reasonably estimate overcharges without need for individualized analysis.

rates to quarters following the alternative generic entry dates. The quarterly generic penetration rates that I have calculated from the actual experience (and then backcast in this fashion) are shown in Exhibit 5.

56. For generic price discounts, I again utilize actual experience following generic entry to model outcomes under the alternative entry scenario. The market went from one generic competitor (Glenmark/Par) in December 2016 to a market with six competitors in June 2017.[76] I use the actual generic discount (relative to brand WAC) that occurred both with one and then with six generic competitors. However, the alternative generic entry scenario also contains periods with two through five competitors (that is, unlike the actual experience, the other five competitors following the initial entrant don't all come into the market at once.) Accordingly, some means for mapping the path of price discounts from one generic competitor (which we observe in the actual experience), through competitors two through five, before reaching competitor six (which we also observe) is needed.

57. [redacted]

58. For my analysis, I [redacted]. I then average those results across the companies to obtain a single predicted generic price discount for each number of generic entrants from one to six.[78] I then use the progression in the

[76] [redacted]

[77] See Section V.B.

[78] I [redacted]

forecast discounts as one moves from one to six competitors to build the progression in discounts (i.e. discounts associated with competitors 2 through 5) from the observed one-competitor discount in the actual generic experience to the observed six-competitor discount in that same experience.

59. My averaging of forecast results is a form of meta-analysis which yields the central tendency of the various company perspectives.[79] In my experience, the use of forecasts in this fashion is both common and accepted practice. Indeed, I have used forecasts to project generic price discounts in a number of cases over the last several years.[80] I note that the results contained within these forecasts are generally reasonable and consistent both with the literature pertaining to the effects of generic competition and my own experience studying generic competition over the last twenty years or so.

60. [redacted]

B. Calculating Aggregate Overcharges

61. I derived actual brand and generic prices, along with volumes, from the transaction data produced by the manufacturers. I then used the benchmarks described above

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[79] The use of averages across many individual forecasts is a well-established method to improve forecast accuracy. See e.g., Clemen, R., "Combining Forecasts: A Review and Annotated Bibliography," *International Journal of Forecasting*, v. 5 (1989), pp. 559-583 at 559 ("[I]n many cases one can make dramatic performance improvements by simply averaging the forecasts."); Batchelor, R., "How Useful Are the Forecasts of Intergovernmental Agencies? The IMF and OECD Versus the Consensus," *Applied Economics*, v. 33, n. 2 (February 2001), pp. 225-235 at 227 ("Just as spreading investments over many assets reduces risk, so averaging forecasts across different forecasters reduces the size of the expected error, a point first formalized by Bates and Granger (1969) almost 30 years ago.").

[80] "Courts have also accepted internal business projections by market actors of excepted prices, sales, or profits for the damages period, formulated before the violation was known or anticipated, as the basis for but-for predictions." *Proving Antitrust Damages, Legal and Economic Issues*, America Bar Association, Third Edition, p. 95 (citations omitted).

[81] [redacted]

for generic discounts and penetration, and brand discounts to implement the overcharge formula described at the beginning of this section.[82] The aggregate Class overcharges associated with but-for entry in July 1, 2012 are presented in Table 1.[83]

Table 1
Aggregate Class Overcharges

	Aggregate Class Overcharges		
But-For Generic Entry	Brand	Generic	Total
	($ Billions)		
			(2) + (3)
(1)	(2)	(3)	(4)
07/01/2012	[redacted]	[redacted]	[redacted]

Source: Manufacturer data; WAC data; manufacturer forecasts (see Appendix A).

62. This formulaic approach to Class-wide overcharges does not require individualized analysis for each Class member. In particular:

- The calculation of actual prices and quantities is based upon the manufacturers' electronic transaction data. This is a class-wide source of evidence common to the Class rather than individual to its members. No investigation into Class member records or collection of data from individual Class members is needed.

[82] The precise implementation differs from the formula as generally presented above in a couple of minor respects. First, the discounts used in this implementation (GD, BD) are calculated relative to brand WAC. Hence the savings relative to the actual prices are adjusted to reflect the fact that the actual prices incorporated discounts relative to WAC. Second, given the actual generic sales that occurred in the post-generic period, the generic penetration relevant to the formula (GP) is the increment to the actual generic penetration that earlier generic entry would have resulted in.

[83] The "Brand" total captures the overcharges associated with increased purchases of lower priced generic in place of the brand and increased discounts on brand volumes that Class members would have continued to purchase absent the challenged conduct. The "Generic" total captures overcharges associated with additional discounts that Class members would have obtained on their purchases of generic Zetia absent the challenged conduct.

- This calculation incorporates single market-wide estimates for generic penetration, generic prices, and brand prices in the but-for world. It is not necessary to examine but-for prices or purchase patterns as to individual Class members.

- The overcharge calculation is performed through a set of computer programs and instructions applied to the manufacturer data jointly and formulaically as to all Class members.[84] No Class member-specific calculations or programs are needed.[85]

C. Other Issues

1. Bypass

63. In this context, the term "bypass" or "generic bypass" is often used to describe the circumstance in which, following generic entry, some Class members' customers buy generics directly from generic manufacturers and "bypass" the wholesaler. Defendants may argue that overcharge volumes need to be adjusted for bypass. Whether or not that adjustment is necessary is ultimately a legal issue. However, assuming that the legal objective in calculating overcharges is to determine the total overcharge created by the challenged conduct, it would then be a mistake as an economic matter to exclude actual Class member purchases that would have moved through different distributors (or distribution channels) under competitive conditions.

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[84] Indeed, the reliability of this overcharge approach is increased by using the over-lapping experience across Class members. In particular, the aggregation serves statistically to reduce the expected error rate (in statistical terms, "standard error") of the estimates. A model of this form also could be used to assess overcharges for individual Class members should that be necessary. This would require some attention to the best means for combining the aggregate findings for pricing and generic substitution with the data for individual Class members.

[85] To the extent that other market factors emerge that must be accounted for in estimating the but-for generic experience (or in estimating a range of alternative but-for generic experiences), the requisite adjustments can be readily incorporated within the Class-wide overcharge formulas. Moreover, to the extent that some economic analysis is needed in coming to the amount of any such Class-wide adjustments, that analysis will, by its nature, be Class-wide. In addition, to the extent that further discovery, findings, or rulings in this case change the inputs to the calculations, including in particular the assumed generic entry dates, this adjustment can be readily incorporated within this Class-wide overcharge model.

64. This is because, assuming Plaintiffs prevail on liability, it will have been demonstrated that Defendants unlawfully delayed generic competition. But for that conduct, generic competition would have displaced the brand volume at prices well below the brand price and potentially generated competitive price reductions for Zetia itself. Class members bore the full brunt of these effects in the amounts they actually paid for Zetia. Hence, to properly capture the full overcharge associated with the challenged conduct, all of that Class purchase volume should be included--even recognizing that some of the price reductions realized under competitive conditions occurs by virtue of generic product that moves through the market outside of the Class. This bypass does not change the identity of the actor (i.e., the Class members) that directly paid the inflated prices for the product in the first place.

65. However, should it be determined legally that overcharges associated with bypassed volumes must be removed from the analysis, this adjustment can be made readily. To do so, one simply reduces the Class's share of the but-for market volumes by the amount of the bypass. I have incorporated such a calculation in some of the work I have done calculating overcharges in other class pharmaceutical cases, though I understand that courts do not require that direct purchasers' damages be reduced to account for bypass.[86]

2. *Alternative but-for entry dates*

66. I also have been asked to consider how different determinations by the jury of the but-for entry dates would affect overcharges (i.e., absent the conduct of the Defendant, the jury estimates that generic entry would have occurred some date after July 2012). I have done so by simply taking the profiles for generic penetration and discounts described above and shifting them in time to account for different initial generic entry dates and, as necessary, different sequencing in the entry of generic competitors.

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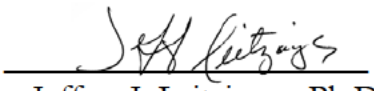
[86] *In re Relafen Antitrust Litigation*, 346 F. Supp. 2d 349, 369 (D. Mass. 2004); *In re Skelaxin (Metaxalone) Antitrust Litigation*, 2014 WL 2002887, at *5-7 (E.D. Tenn. May 15, 2014); *In re Niaspan Antitrust Litigation*, No. 13-MD-2460, 2015 WL 4197590, at *1-2 (E.D. Pa. July 9, 2015); *In re Prograf Antitrust Litigation*, No. 1:11-MD-02242-RWZ, 2014 WL 7641156, at *4 (D. Mass. Dec. 23, 2014); *In re Loestrin 24 FE Antitrust Litigation*, MDL No. 13-2472, 2019 WL 3214257, at *5-6 (D.R.I. July 2, 2019); *In re Namenda Direct Purchaser Antitrust Litigation*, No. 15 Civ. 7488-CM-RWL, at p. 20 (S.D.N.Y. August 2, 2019).

67. The ability to adjust for these effects based upon differing but-for entry dates is embedded formulaically in the computer program that calculates the overcharges. To account for differing but-for entry dates within the overcharge model, it is a straightforward matter of adjusting the computerized overcharge program. To illustrate the ease with which the overcharge model can be adjusted to account for various assumed entry dates, I have calculated overcharges for various but-for entry dates between July 1, 2012 and June 26, 2015. See Exhibit 10. These figures are presented in Exhibits 11A and 11B.



Jeffrey J. Leitzinger, Ph.D.
November 18, 2019

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EDUCATION

Ph.D., Economics, University of California, Los Angeles
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WORK EXPERIENCE

Econ One Research, Inc., 1997 to date
Board Chairman and Managing Director, 2018 to date
Management Committee Chair, 2012-2018
President and CEO, 1997-2011
Founder, 1997

Micronomics, Inc., 1988-1997
President and CEO, 1994-1997
Executive Vice President, 1988-1994
Cofounder, 1988

National Economic Research Associates, Inc. 1980-1988
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California State University, Northridge, Lecturer, 1979-1980

AREAS OF EXPERTISE

Has offered expert testimony regarding:

- Competition economics
- Commercial damages
- Econometrics and statistics

- Intellectual property
- Valuation

INVITED PRESENTATIONS

Some Implications of Tyson for Econometric Models in Class Action Antitrust Cases, *American Bar Association,* 65th Antitrust Law Spring Meeting, March 2017.

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Innovation in Regulation, *Center for Research in Regulated Industries*, 11th Annual Western Conference, July/September 1998.

Electric Industry Deregulation: What Does the Future Hold?, *Los Angeles Headquarters Association,* November 1996.

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Techniques in the Direct and Cross-Examination of Economic, Financial, and Damage Experts, *The Antitrust and Trade Regulation Law Section of the State Bar of California and The Los Angeles County Bar Association*, 2nd Annual Golden State Antitrust and Trade Regulation Institute, October 1994.

Demonstration: Deposition of Expert Witnesses and Using Legal Technology, *National Association of Attorneys General*, 1994 Antitrust Training Seminar, September 1994.

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Price Premiums in Gas Purchase Contracts, *International Association for Energy Economics,* October 1992.

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Dr. Jeffrey Leitzinger
November 2015 – October 2019

	Proceeding	Court/Commission/ Agency	Docket or File
1.	In Re: Wholesale Grocery Products Antitrust Litigation	U.S. District Court, District of Minnesota	Civil Action No. 09-md-02090 ADM/AJB, 09-md-02090 ADM/TNL
2.	In Re: AndroGel Antitrust Litigation	U.S. District Court, Northern District of Georgia	Case No. 1:09-MD-2084-TWT
3.	In Re: Rail Freight Surcharge Antitrust Litigation	U.S. District Court, District of Columbia	Case No. 1:07-MC-00489
4.	In Re: Lidoderm Antitrust Litigation	U.S. District Court, Northern District of California	No. 14-MD-02521-WHO
5.	Social Ranger, LLC v. Facebook, Inc.	U.S. District Court, District of Delaware	C.A. No. 14-1525-LPS
6.	UFCW & Employers Benefit Trust, et al., v. Sutter Health, et al.	Superior Court of California, County of San Francisco	No. CGC 14-538451 No. CGC-18-565398
7.	Merced Irrigation District v. Barclay's Bank, PLC	U.S. District Court, Southern District of New York	No. 1:15-cv-04878-VM-GWG
8.	In re: Celebrex (Celecoxib) Antitrust Litigation	U.S. District Court, Eastern District of Virginia, Norfolk Division	Civil Action No. 14-cv-00361
9.	Sourceone Dental Inc. v. Patterson Companies, et al.	U.S. District Court, Eastern District of New York	Case No. 15-cv-05440
10.	In Re Solodyn (Minocycline Hydrochloride) Antitrust Litigation	U.S. District Court, District of Massachusetts	MDL No. 14-md-2503-DJC
11.	In re: Thalomid and Revlimid Antitrust Litigation	U.S. District Court, District of Connecticut	C.A. No. 3:14-MD-2516 (SRU)
12.	In re Loestrin 24 FE Antitrust Litigation	U.S. District Court, District of Rhode Island	MDL No. 2472, Master File No. 1:13-md-2472-S-PAS

Dr. Jeffrey Leitzinger
November 2015 – October 2019

	Proceeding	Court/Commission/ Agency	Docket or File
13.	CVS Health Corporation, Caremark, LLC, and Caremark, PCS, LLC v. Vividus LLC f/k/a HM Compounding Services, LLC, and HMX Services, LLC d/b/a HM Compounding	American Arbitration Association	Case No. 01-14-0002-0801
14.	In Re: Qualcomm Litigation	U.S. District Court, Southern District of California	Case No. 3:17-cv-00108-GPC-MDD
15.	In re: Niaspan Antitrust Litigation	U.S. District Court, Eastern District of Pennsylvania	MDL 2460, Master Case No. 2:13-md-2460
16.	Littop Enterprises Limited, et al. v. Ukraine	The Stockholm Chamber of Commerce	SCC Case No 2015/092
17.	In re: Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litigation	U.S. District Court, Eastern District of New York	Case No. 18-MD-2819 (NG) (LB)
18.	In re: Opana ER Antitrust Litigation	U.S. District Court, Northern District of Illinois	Civil Action No. 14-cv-10150
19.	In re: Intuniv Aititrust Litigation	U.S. District Court, District of Massachusetts	Civil Action No. 16-cv-12653-ADB (Direct)
20.	SS&C Technologies, Inc. v. Clearwater Analytics, LLC	Superior Court for the State of Connecticut, Judicial District of Hartford	No. X07-HHD-CV-16-6070719-S

Exhibit 2
In Re: Zetia Antitrust Litigation
List of Materials Reviewed

Includes all documents, studies, and articles cited in the Declaration.

Pleadings and Opinions

D RECT PURCHASER PLA NTIFFS' CONSOL DATED CLASS ACTION COMPLA NT AND DEMAND FOR JURY TRIAL (09/05/2018)
DEFENDANTS' FIRST SET OF REQUESTS FOR ADMISSION TO PLAINT FFS (05/06/2019)
D RECT PURCHASER PLA NTIFFS' AMENDED CONSOLIDATED CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL (06/27/2019)
DEFENDANTS MERCK & CO., INC., MERCK SHARP & DOHME CORP., SCHERING-PLOUGH CORP., SCHERING CORP., AND MSP SINGAPORE CO. LLC RESPONSE TO D RECT PURCHASER PLA NTIFFS' MOTION FOR CLASS CERTIFICATION FOR PURPOSES OF SETTLEMENT WITH PAR PHARMACEUTICAL, INC., AND PREL MINARY APPROVAL OF PROPOSED SETTLEMENT (07/29/2019)
In re ZETIA (EZET MIBE) ANTITRUST LITIGATION, REPORT AND RECOMMENDATION (10/01/2019)
In re ZETIA (EZET MIBE) ANTITRUST LITIGATION, REPORT AND RECOMMENDATION (10/15/2019)

Depositions and/or Exhibits

Brown, Lawrence M. (10/24/2019)
Davish, Patrick T. (09/11/2019)
Dutra, Paul G. (09/26/2019)
Exume, Myriam (09/19/2019)
Jankiewicz, David (11/06/2019)
Koleto, Christina (10/17/2019)
Pakula, David (09/26/2019)

Documents

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Exhibit 2
In Re: Zetia Antitrust Litigation
List of Materials Reviewed

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Exhibit 2
In Re: Zetia Antitrust Litigation
List of Materials Reviewed

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List of Materials Reviewed

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In Re: Zetia Antitrust Litigation
List of Materials Reviewed

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AUROBINDO
- Ezetimibe Credit Note line report- Rebates-Launch t o March 2019.xlsx
- Ezetimibe sales data - Final till March 2019.xlsx
- Ezetimide NDCs 10.1.17 to 3.31.18-Chargeback data.xlsx
- Ezetimide NDCs 12.1.18 to 3.31.19-Chargeback data.xlsx
- Ezetimide NDCs 4.1.18 to 11.30.18-Chargeback data.xlsx

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Public Data
- Medi-Span (WAC)
- IMS IQVIA

Exhibit 2
In Re: Zetia Antitrust Litigation
List of Materials Reviewed

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In re Prograf Antitrust Litig., No. 1:11-MD-02242-RWZ, 2014 WL 7641156, (D. Mass. Dec. 23, 2014).
In re Relafen Antitrust Litigation, Master File No. 01-12239-WGY, (D. Mass.).
In re Skelaxin (Metaxalone) Antitrust Litigation, 2014 WL 2002887, (E D. Tenn. May 15, 2014).
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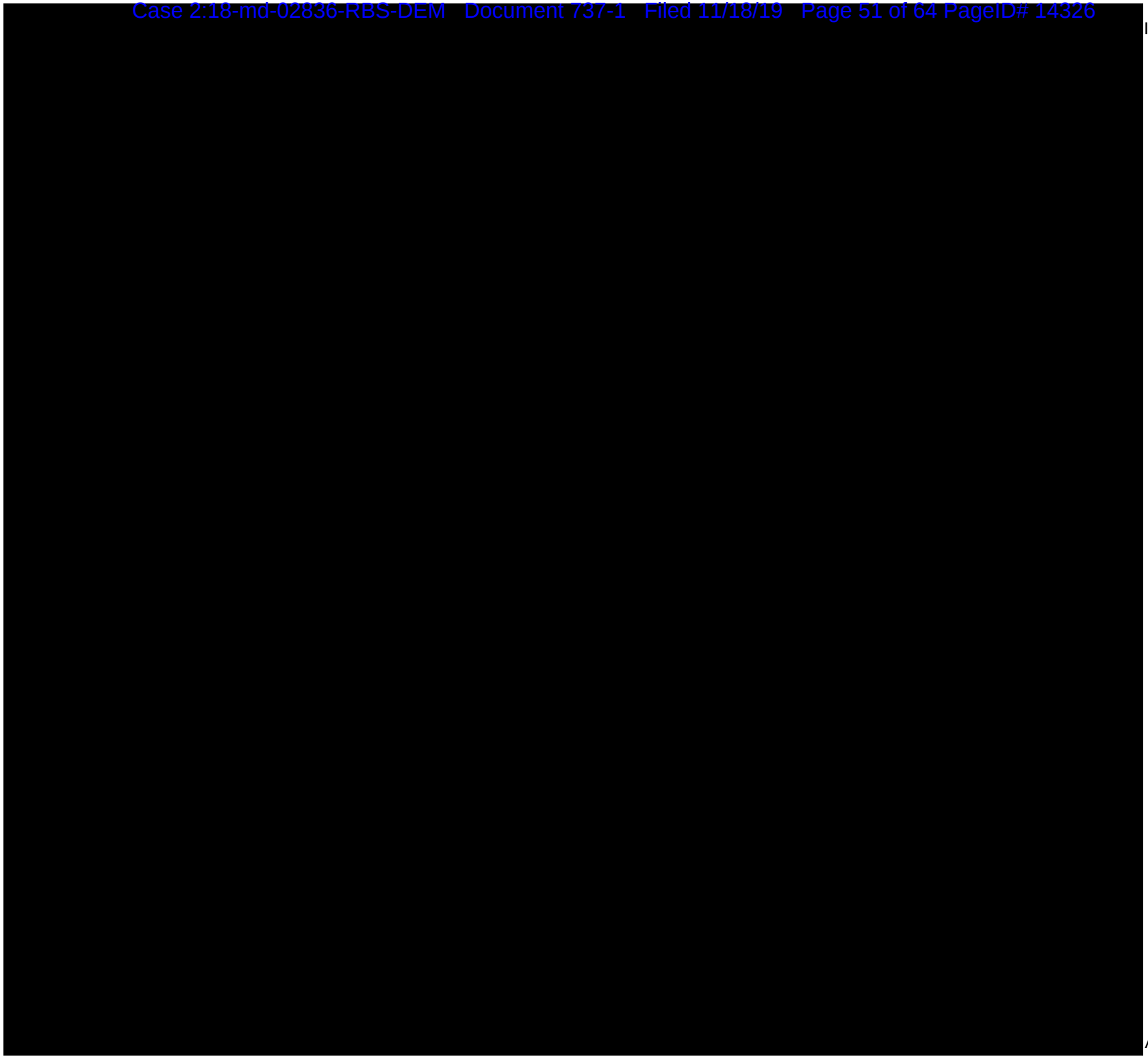
Other

21 USC § 355
H R. Rep. 98-857 (I), 1984 U.S.C.C.A N. 2647

IDENTIAL



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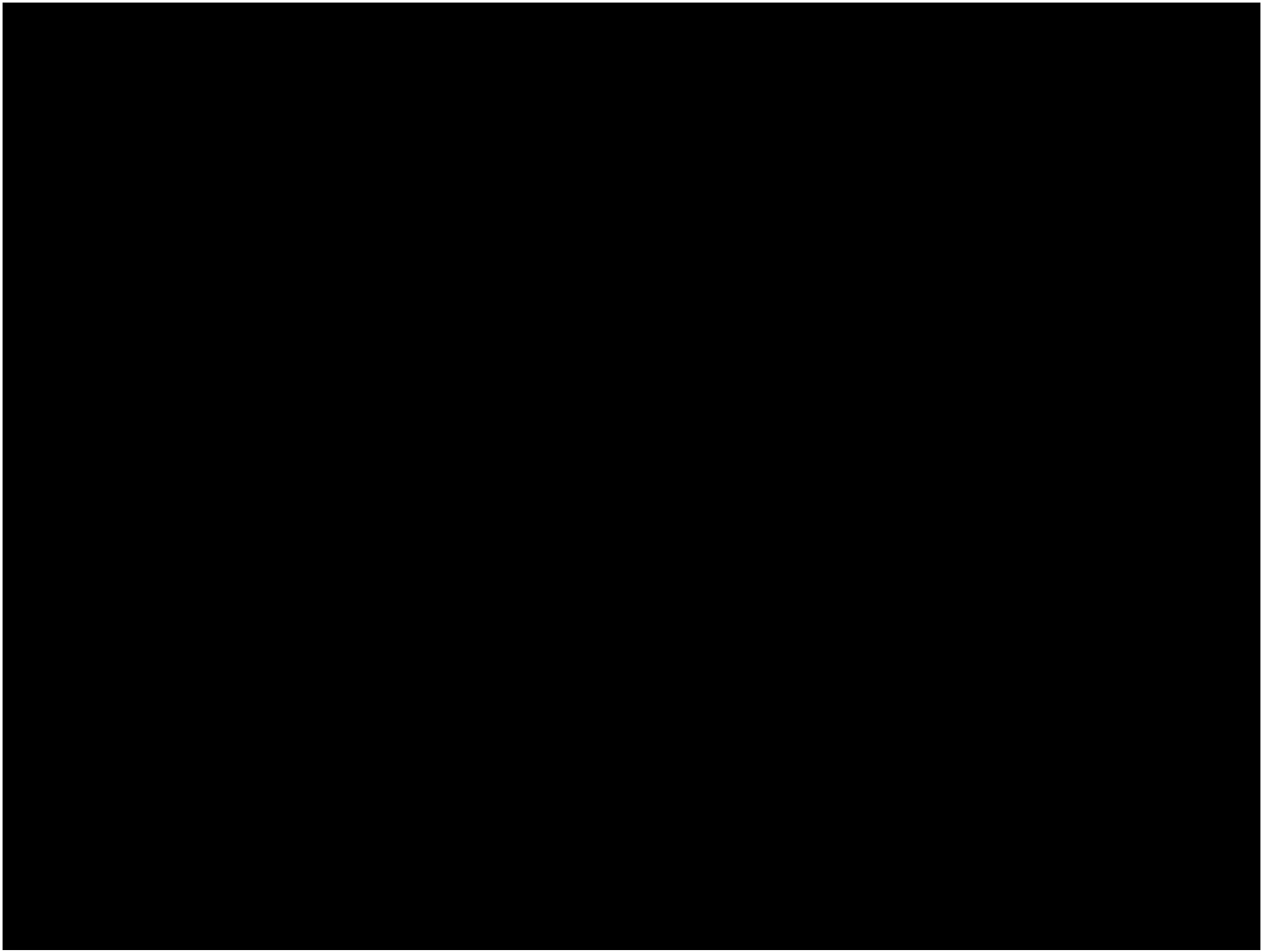


Exhibit 5
Class Generic Penetration Rate

Quarter After Generic Entry	Class Generic Penetration Rate (Percent)
[redacted]	

[redacted]

Exhibit 7
But-For Entry Scenario

But-For Generic Entry Date:						
Glenmark and AG	Third Generic Entrant	Fourth Generic Entrant	Fifth Generic Entrant	Sixth, Seventh, Eighth, Ninth Generic Entrants	Tenth Generic Entrant	Eleventh Generic Entrant
(1)	(2)	(3)	(4)	(5)	(6)	(7)
07/01/2012	11/13/2015	12/15/2015	02/16/2016	06/12/2017	08/25/2017	12/21/2017

Exhibit 8
List of Class Members

Class Member

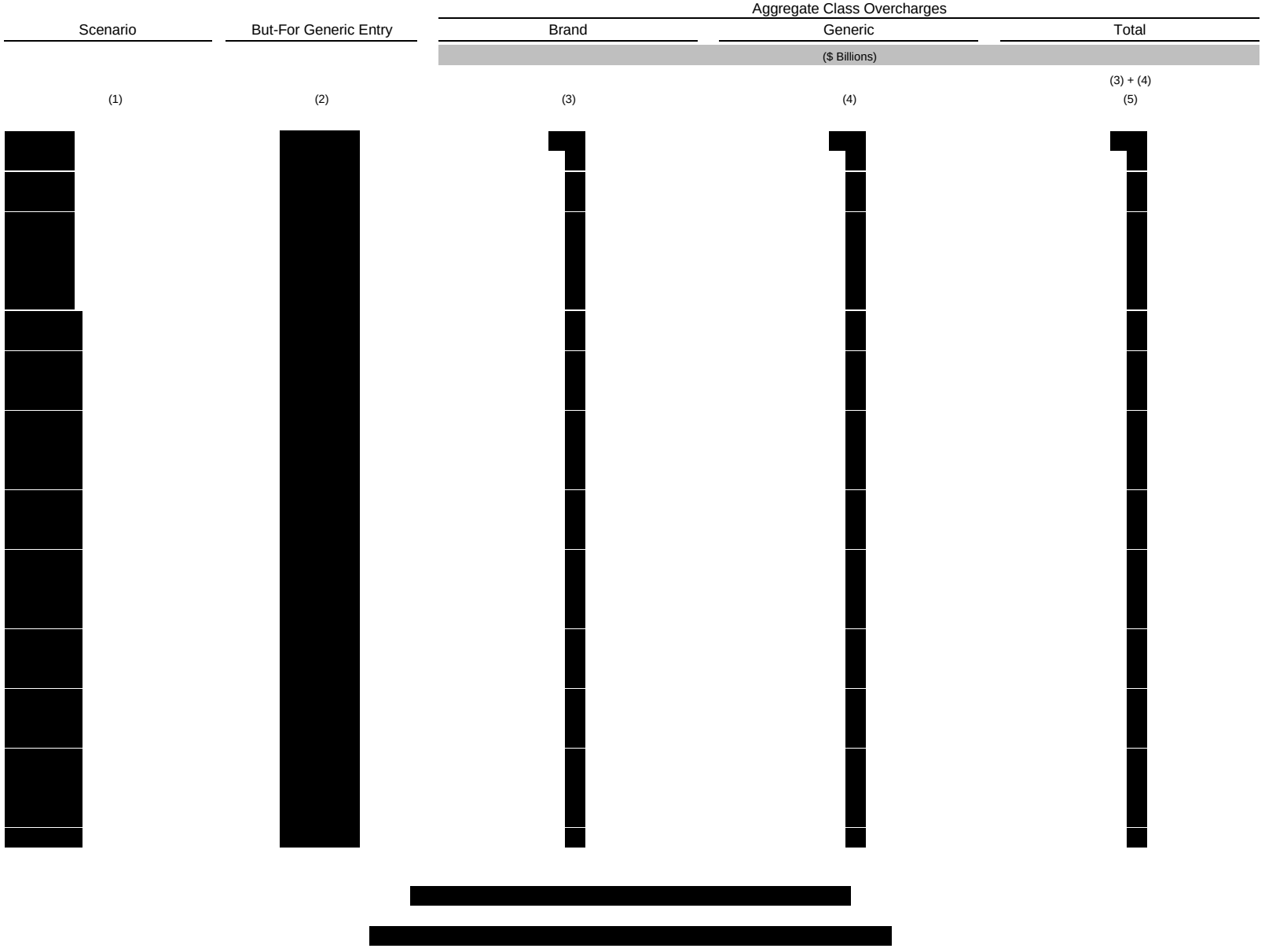
[redacted]

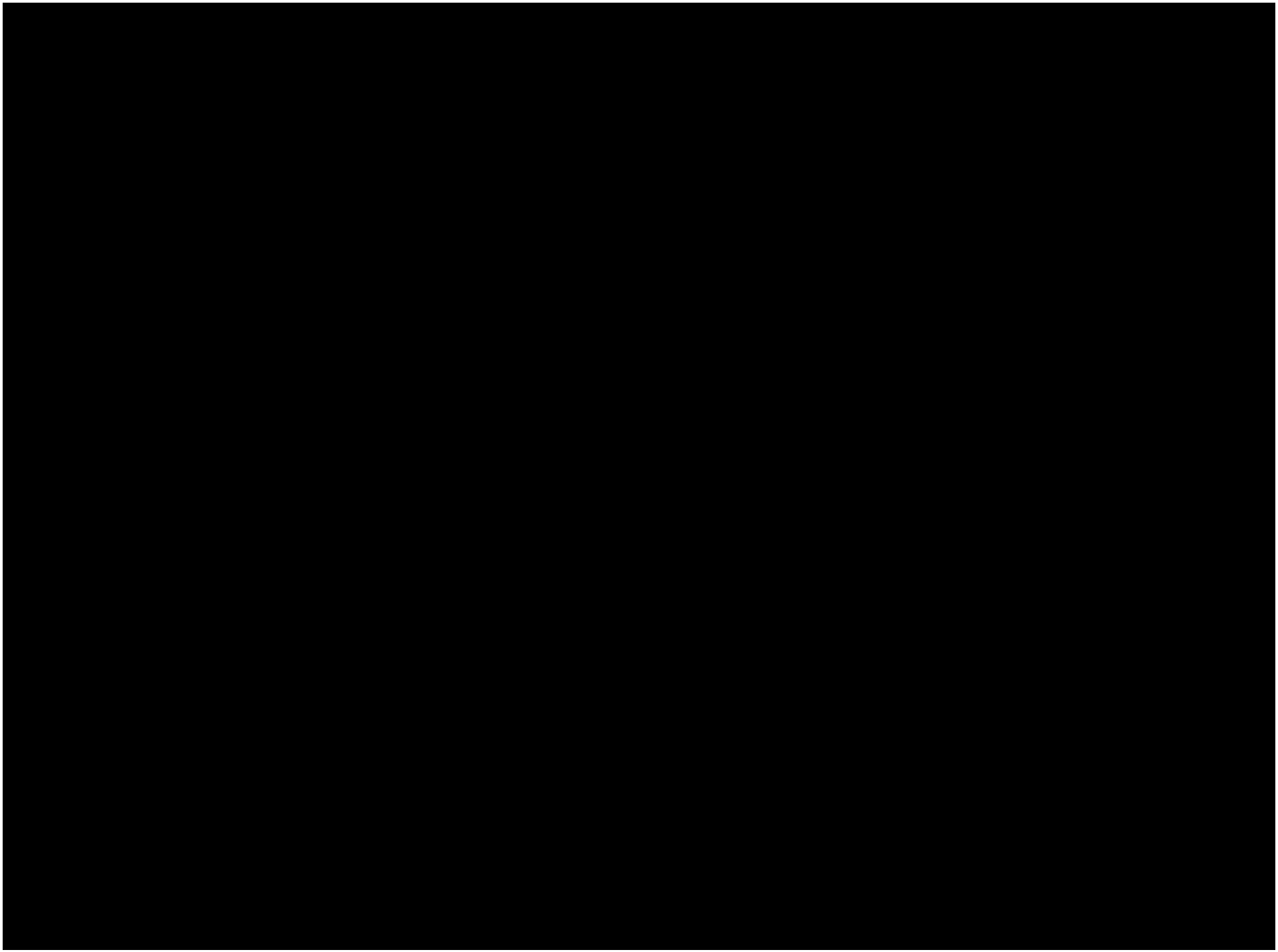
Exhibit 9
Class Member Locations

Exhibit 10
But-For Entry Scenarios

	But-For Generic Entry Date:					
Glenmark and AG	Third Generic Entrant	Fourth Generic Entrant	Fifth Generic Entrant	Sixth, Seventh, Eighth, Ninth Generic Entrants	Tenth Generic Entrant	Eleventh Generic Entrant
(1)	(2)	(3)	(4)	(5)	(6)	(7)
Monthly from 07/01/2012 through 05/01/2015	11/13/2015	12/15/2015	02/16/2016	06/12/2017	08/25/2017	12/21/2017
6/26/2015	12/23/2015	12/23/2015	02/16/2016	06/12/2017	08/25/2017	12/21/2017

Exhibit 11A
Range of Aggregate Class Overcharges





Appendix A
Manufacturer Forecasts Used in Overcharge Calculation

Apotex: APOTEX0000064-APOTEX0000072.
APOTEX0000073-APOTEX0000082.
APOTEX0000083-APOTEX0000092.
APOTEX0000093-APOTEX0000101.
APOTEX0000102-APOTEX0000112.
APOTEX0000113-APOTEX0000122.

Glenmark: GLENMARK-ZETIA-00176817;
- GLENMARK-ZETIA-00177463 (duplicate);
- GLENMARK-ZETIA-00187331 (duplicate);
- GLENMARK-ZETIA-00194738 (duplicate);
- GLENMARK-ZETIA-00199685 (duplicate);
- GLENMARK-ZETIA-00214438 (duplicate);
- GLENMARK-ZETIA-00214449 (duplicate).
- GLENMARK-ZETIA-00214703 (duplicate);
- GLENMARK-ZETIA-00237133 (duplicate);
- GLENMARK-ZETIA-00237140 (duplicate).

GLENMARK-ZETIA-00176853.
GLENMARK-ZETIA-00177411;
- GLENMARK-ZETIA-00177557 (duplicate);
- GLENMARK-ZETIA-00200092 (duplicate);
- GLENMARK-ZETIA-00200094 (duplicate);
- GLENMARK-ZETIA-00202088 (duplicate);
- GLENMARK-ZETIA-00214881 (duplicate).

GLENMARK-ZETIA-00177486;
- GLENMARK-ZETIA-00202054 (duplicate);
- GLENMARK-ZETIA-00214456 (duplicate);
- GLENMARK-ZETIA-00214477 (duplicate).

GLENMARK-ZETIA-00178590.
GLENMARK-ZETIA-00199718.
GLENMARK-ZETIA-00199888;
- GLENMARK-ZETIA-00199712 (duplicate).

GLENMARK-ZETIA-00202055;
- GLENMARK-ZETIA-00214457 (duplicate).

GLENMARK-ZETIA-00202253;
- GLENMARK-ZETIA-00216824 (duplicate).

GLENMARK-ZETIA-00211772;
- GLENMARK-ZETIA-00211909 (duplicate);
- GLENMARK-ZETIA-00234782 (duplicate).

GLENMARK-ZETIA-00214483;
- GLENMARK-ZETIA-00177499 (duplicate);
- GLENMARK-ZETIA-00214759 (duplicate).

GLENMARK-ZETIA-00214760.
GLENMARK-ZETIA-00217629;
- GLENMARK-ZETIA-00199052 (duplicate);
- GLENMARK-ZETIA-00282244 (duplicate).

GLENMARK-ZETIA-00219452;
- GLENMARK-ZETIA-00240142 (duplicate).

GLENMARK-ZETIA-00234719.
GLENMARK-ZETIA-00237212;
- GLENMARK-ZETIA-00199710 (duplicate).

GLENMARK-ZETIA-00256697;
- GLENMARK-ZETIA-00242022 (duplicate).

GLENMARK-ZETIA-00282331;
- GLENMARK-ZETIA-00217627 (duplicate);
- GLENMARK-ZETIA-00165527 (duplicate).

Koleto Exhibit 6; Dutra Exhibit 9 (GLENMARK-ZETIA-00202268);
- GLENMARK-ZETIA-00202266 (duplicate);
- GLENMARK-ZETIA-00216215 (duplicate).

Koleto Exhibit 8; Dutra Exhibit 8 (GLENMARK-ZETIA-00202257);
- GLENMARK-ZETIA-00202262 (duplicate);
- GLENMARK-ZETIA-00216207 (duplicate);
- GLENMARK-ZETIA-00216210 (duplicate).

Koleto Exhibit 10; Dutra Exh bit 11 (GLENMARK-ZETIA-00202294);
- GLENMARK-ZETIA-00216822 (duplicate).

Appendix A
Manufacturer Forecasts Used in Overcharge Calculation

Koleto Exhibit 12 (GLENMARK-ZETIA-00156103).
Koleto Exhibit 14 (GLENMARK-ZETIA-00178561);
- GLENMARK-ZETIA-00199291 (duplicate);
- GLENMARK-ZETIA-00217630 (duplicate);
- GLENMARK-ZETIA-00237344 (duplicate);
- GLENMARK-ZETIA-00254080 (duplicate);
- GLENMARK-ZETIA-00277584 (duplicate);
- GLENMARK-ZETIA-00282333 (duplicate).

Merck: Jankiewicz Exh bit 2; Pakula Exhibit 25 (MRKZETIA000509916).
Jankiewicz Exh bit 3; Pakula Exhibit 26 (MRKZETIA000509917).

Mylan: MRKZETIA_SIDLEY000105916;
- MRKZETIA_SIDLEY000214899 (duplicate).

MRKZETIA_SIDLEY000198087.
MRKZETIA_SIDLEY000215596.
MRKZETIA_SIDLEY000215597.
MRKZETIA_SIDLEY000215598.
MRKZETIA_SIDLEY000215599.
MRKZETIA_SIDLEY000215600;
- MRKZETIA_SIDLEY000215605 (duplicate).

MRKZETIA_SIDLEY000215602.
MRKZETIA_SIDLEY000215603.
MRKZETIA_SIDLEY000215604.
MRKZETIA_SIDLEY000215606.
MRKZETIA_SIDLEY000215608.
MRKZETIA_SIDLEY000215609.
MRKZETIA_SIDLEY000221516.
MRKZETIA_SIDLEY000221517.
MYL_ZETIA011618-MYL_ZETIA012075;
- MYL_ZETIA012079-MYL_ZETIA012088 (duplicate).

Par: Brown Exhibit 32 (PAR_00007867).
Brown Exhibit 33 (PAR_00008221).
Brown Exhibit 34 (PAR_00008143);
- PAR_00021843 (duplicate).

Brown Exhibit 35 (PAR_00008127).
Brown Exhibit 36 (PAR_00008076);
- GLENMARK-ZETIA-00261529 (duplicate).
- PAR_00008083 (duplicate);

Brown Exhibit 37 (PAR_00007273);
- PAR_00007284 (duplicate);
- PAR_00007496 (duplicate);
- PAR_00007905 (duplicate).

Brown Exhibit 38 (PAR_00005375);
- PAR_00013911 (duplicate).

Brown Exhibit 39 (PAR_00002330);
- GLENMARK-ZETIA-00202402 (duplicate);
- GLENMARK-ZETIA-00211950 (duplicate);
- GLENMARK-ZETIA-00214784 (duplicate);
- PAR_00004234 (duplicate);
- PAR_00015157 (duplicate).

GLENMARK-ZETIA-00165847.
GLENMARK-ZETIA-00167079;
- GLENMARK-ZETIA-00168202 (duplicate);
- GLENMARK-ZETIA-00168254 (duplicate);
- GLENMARK-ZETIA-00168529 (duplicate);
- GLENMARK-ZETIA-00217692 (duplicate);
- GLENMARK-ZETIA-00259691 (duplicate);
- GLENMARK-ZETIA-00282337 (duplicate);
- PAR_00021367 (duplicate).

Appendix A
Manufacturer Forecasts Used in Overcharge Calculation

GLENMARK-ZETIA-00176836;
- GLENMARK-ZETIA-00177478 (duplicate);
- GLENMARK-ZETIA-00178563 (duplicate);
- GLENMARK-ZETIA-00192603 (duplicate);
- GLENMARK-ZETIA-00199034 (duplicate);
- GLENMARK-ZETIA-00199279 (duplicate);
- GLENMARK-ZETIA-00214454 (duplicate);
- GLENMARK-ZETIA-00214723 (duplicate);
- GLENMARK-ZETIA-00217635 (duplicate);
- GLENMARK-ZETIA-00237238 (duplicate);
- GLENMARK-ZETIA-00282284 (duplicate);
- PAR_00000503 (duplicate);
- PAR_00019197 (duplicate);
- PAR_00019296 (duplicate).

GLENMARK-ZETIA-00177280;
- GLENMARK-ZETIA-00178558 (duplicate);
- GLENMARK-ZETIA-00186375 (duplicate);
- GLENMARK-ZETIA-00186646 (duplicate);
- GLENMARK-ZETIA-00195202 (duplicate);
- GLENMARK-ZETIA-00198555 (duplicate);
- GLENMARK-ZETIA-00202136 (duplicate);
- GLENMARK-ZETIA-00214885 (duplicate).

GLENMARK-ZETIA-00178557;
- GLENMARK-ZETIA-00186342 (duplicate);
- GLENMARK-ZETIA-00195160 (duplicate);
- PAR_00008379 (duplicate);
- PAR_00016088 (duplicate);
- PAR_00016106 (duplicate);
- PAR_00016381 (duplicate).

GLENMARK-ZETIA-00199723;
- GLENMARK-ZETIA-00176795 (duplicate);
- GLENMARK-ZETIA-00199890 (duplicate);
- GLENMARK-ZETIA-00213545 (duplicate);
- PAR_00001545 (duplicate).

GLENMARK-ZETIA-00202383;
- GLENMARK-ZETIA-00213598 (duplicate);
- GLENMARK-ZETIA-00214808 (duplicate);
- GLENMARK-ZETIA-00241676 (duplicate);
- GLENMARK-ZETIA-00267725 (duplicate);
- GLENMARK-ZETIA-00275752 (duplicate).

GLENMARK-ZETIA-00211818.
GLENMARK-ZETIA-00214485.
GLENMARK-ZETIA-00217680;
- GLENMARK-ZETIA-00167597 (duplicate).

GLENMARK-ZETIA-00217687.
GLENMARK-ZETIA-00217703.
Koleto Exhibit 15 (GLENMARK-ZETIA-00165621);
- GLENMARK-ZETIA-00167778 (duplicate).

PAR_00000653.
PAR_00002332;
- PAR_00014594 (duplicate).

PAR_00002915;
- PAR_00002918 (duplicate);
- PAR_00002921 (duplicate);
- PAR_00002930 (duplicate);
- PAR_00002934 (duplicate).
- PAR_00003644 (duplicate);
- PAR_00004455 (duplicate);
- PAR_00004468 (duplicate).

PAR_00003366.
PAR_00003509;
- PAR_00003512 (duplicate).

PAR_00005152;
- PAR_00013890 (duplicate);
- PAR_00013892 (duplicate).

Appendix A
Manufacturer Forecasts Used in Overcharge Calculation

PAR_00007332.
PAR_00008449.
PAR_00014542.
PAR_00018432.
PAR_00018435.
PAR_00018438.
PAR_00018770.
PAR_00019291.
PAR_00019333.
PAR_00021842.

Prasco: PRASCO000081.

Sandoz: SANDOZ-ZETIA-0000001.
SANDOZ-ZETIA-0000003.

Teva: TEVA-ZETIA_00003525.
TEVA-ZETIA_00003526;
TEVA-ZETIA_00003527 (duplicate).
TEVA-ZETIA_00003528.
TEVA-ZETIA_00003529.
TEVA-ZETIA_00003530.
TEVA-ZETIA_00003531;
TEVA-ZETIA_00003532 (duplicate).
TEVA-ZETIA_00003533.